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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,744	08/18/2000	Brian F. Tack	IOWA:026US	7819

7590 03/26/2003

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/642,744	TACK ET AL.	
	Examin r	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *2 and 4-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' amendment B, received December 2, 2002, paper 18 is acknowledged. . Claims 1 and 3 were amended.

2. Currently claims 1-31 are pending

3. Claims 2, 4-31 are withdrawn from further consideration pursuant to37 CFR 1.142(b), as being drawn to non-elected inventions.

4. Claims 1 and 3 are under consideration.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

6. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Objections Maintained

7. Objections to the drawings made in paragraph 6 of the office action mailed 7/29/2002, paper #16 are maintained. No amendments to the drawings were submitted. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Rejections Withdrawn

8. Rejection of claims 1 and 3 under 35 U.S.C. 112, second paragraph made in paragraph 7 of

the office action mailed 7/29/2002, paper #16 is withdrawn in view of applicants' amendment of the claims.

Rejections Maintained

8. Rejection of claims 1 and 3 under 35 U.S.C. (102) b made in paragraph 8 of the office action mailed 7/29/2002, paper #16 is maintained.

The rejection was as stated below:

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahoney et al. (FEBS Letters, Vol.377, pp. 519-522, 1995) prior art already made of record in applicants' 1449.

Claims 1 and 3 are drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Mahoney et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 2 and attached sequence alignments Accession numbers S68411 and S68412). Mahoney et al. also teach sterile water as pharmaceutically acceptable carrier (see material and methods). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments of 12/02/ 2002 have been carefully considered but they are not

deemed persuasive.

Applicants argue that In re Best and In re Fitzgerald are not applicable here. Applicants also argue that prior art discloses a polypeptide of 152 residues and applicants have amended the claims by inserting an "upper length" for the peptides of no more 50 residues. Thus the subject matter as now claimed cannot be identical to that disclosed in the cited reference.

It is the examiner's position that the claimed invention is still anticipated by the prior art of Mahoney et al.The prior art anticipates the claimed invention by disclosing a cathelin- related protein 2 # status predicted residues 124-152 (not more than 50 residues) with the same or similar characteristics as claimed (see attached sequence alignment, page 1, result 1 highlighted with blue ink). The compositions in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same, the compositions of Mahoney et al. would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the compositions of the prior art are evidenced to meet the limitations of the claimed compositions, in the absence of evidence to the contrary.

9. Rejection of claim 1 under 35 U.S.C. (102) b made in paragraph 9 of the office action mailed 7/29/2002, paper #16 is maintained.

The rejection was as stated below:

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bagella et al. (FEBS Letters, Vol.376, pp. 225-228, 1995) prior art already made of record in applicants' 1449.

Claim 1 is drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Bagella et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 1, section B and attached sequence alignment Accession number S68228). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments of 12/02/ 2002 have been carefully considered but they are not deemed persuasive.

Applicants argue that In re Best and In re Fitzgerald are not applicable here. Applicants also argue that prior art discloses a polypeptide of 160 residues and applicants has amended the claims by inserting an "upper length" for the peptides of no more 50 residues. Thus the subject matter as now claimed cannot be identical to that disclosed in the cited reference.

It is the examiner's position that the claimed invention is still anticipated by the prior art of Bagella et al. The prior art anticipates the claimed invention by disclosing a myeloid antibacterial peptide 29 # status predicted residues 132-160 (not more than 50 residues) with the same or similar characteristics as claimed (see attached sequence alignment, page 2, result 2 highlighted with blue ink). The compositions in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same, the compositions

of Bagella et al. would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the compositions of the prior art are evidenced to meet the limitations of the claimed compositions, in the absence of evidence to the contrary.

10. Rejection of claims 1 and 3 under 35 U.S.C. (102) b made in paragraph 10 of the office action mailed 7/29/2002, paper #16 is maintained.

The rejection was as stated below:

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Merluzzi et al. (Peptides, Vol.261, pp. 639-640, 1996) prior art already made of record in applicants' 1449.

Claims 1 and 3 are drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Merluzzi et al. teach isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see page 639). Merluzzi et al. also teach water as pharmaceutically acceptable carrier (see page 640). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments of 12/02/ 2002 have been carefully considered but they are not

deemed persuasive.

Applicants argue that In re Best and In re Fitzgerald are not applicable here. Applicants also argue that prior art discloses a polypeptide of 160 residues and applicants has amended the claims by inserting an "upper length" for the peptides of no more 50 residues. Thus the subject matter as now claimed cannot be identical to that disclosed in the cited reference.

It is the examiner's position that the claimed invention is still anticipated by the prior art of Merluzzi et al. The prior art anticipates the claimed invention by disclosing a sheep myeloid antimicrobial peptide of 29 residues (not more than 50 residues), which has been named SMAP 29 (see page 639 under results and discussions). The compositions in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same, the compositions of Merluzzi et al. would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the compositions of the prior art are evidenced to meet the limitations of the claimed compositions, in the absence of evidence to the contrary.

New Grounds for rejection

New Matter Rejection

11. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims now include the newly added limitation " not more than 50 residues". However, there appears to be no descriptive support in the instant specification for this added limitation. 37 CFR 1.121 requires that an amendment to the claim must have antecedent basis in the original disclosure. Therefore the new limitation in the claim is considered new matter. *In re Rasussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, B.S. Pharm, M.S.

Biotechnology Patent Examiner

Art Unit 1645
March 24, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600